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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,828	12/21/2001	Tiecheng A. Qiao	82917WFN	4935

7590 11/12/2004

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,828	QIAO ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 21 September 2004 in which claims 1, 5, 7 and 21 were amended and a Declaration under 37 C.F.R. § 1.131 was submitted. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 21 June 2004 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are withdrawn in view of the Declaration. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the Declaration, are discussed.

Claims 1-25 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 8-12 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998).

Regarding Claim 1, Sutton et al discloses a method for detecting biological samples comprising providing a microarray including a substrate having no preselected sites for microsphere association (Fig. 2-7), coated with a composition of microspheres dispersed in a

fluid containing a gelling agent (e.g. polyacrylamide, Column 11, lines 53-57 and Column 12, lines 17-23) the microspheres immobilized at random position on the substrate (Fig. 2-7) and at lease one sub-population of microspheres contain an optical barcode generated from at least one colorant "associated" with the microspheres (i.e. dye in the coating composition, Column 11, line 57) and further contain a biological probe (e.g. antibody, Column 11, lines 53-57). Sutton et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 16 and Example 1).

Regarding Claim 8, Sutton et al disclose the method wherein the substrate is characterized by an absence of specific sites capable of interacting with the microspheres (Fig. 2-7).

Regarding Claim 9, Sutton et al disclose the method wherein the microsphere has active sites with probes (Column 5, line 32-Column 6, line 28).

Regarding Claims 10-12, Sutton et al disclose the method wherein the microspheres have a diameter of 5 μm (Column 5, lines 30-32 and Column 11, line 55).

Regarding Claim 16-18, Sutton et al disclose the method wherein the microspheres comprise amorphous polystyrene (Column 6, lines 29-54).

Regarding Claim 19, Sutton et al disclose the method wherein the microspheres comprise a polymeric material and less than 30% weight crosslinking material (Column 6, lines 28-64).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2-4, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998) in view of Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001).

Regarding Claims 2-4, Sutton et al discloses a method for detecting biological samples comprising providing a microarray including a substrate having no preselected sites for microsphere association (Fig. 2-7), coated with a composition of microspheres dispersed in a fluid containing a gelling agent (e.g. polyacrylamide, Column 11, lines 53-57 and Column 12, lines 17-23) the microspheres immobilized at random position on the substrate (Fig. 2-7) and at lease one sub-population of microspheres contain an optical barcode generated from at least one colorant "associated" with the microspheres (i.e. dye in the coating composition, Column 11, line 57) and further contain a biological probe (e.g. antibody, Column 11, lines 53-57). Sutton et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 16 and Example 1). Sutton et al teach the method wherein the biological sample is identified by detecting color associated with a sub-population of microspheres (Claim 16) but they do not teach a plurality of sub-populations each having a unique barcode (Claim 2) the color is generated by two or more colorants (Claim 3) i.e. a mixture of fed, green and blue (Claim 4). However, these elements were well known in the art at the time the claimed invention was made as taught by Walt et al. Walt et al teach a similar method comprising a microarray having microsphere sub-populations at random positions (Column 4, lines 35-58) wherein each sub-population have a unique bar code and unique biological probe generated from a mixture of red, green and blue (Column 14, lines 24-67) wherein the multiple bar code coloring enables encoding of a large number of functionalities while using a small number of colors (Column 14, lines 60-67). It would have been obvious to one of ordinary skill in the art

at the time the claimed invention was made to apply the plurality of optical bar codes of Walt et al to the microspheres of Sutton et al for the expected benefit of encoding of a large number of functionalities while using a small number of colors as taught by Walt et al (Column 14, lines 60-67).

Regarding Claim 13-15, Sutton et al is silent regarding the concentration of microspheres on the substrate. However, the claims concentrations were well known in the art at the time the claimed invention was made as taught by Walt (Column 4, line 66-Column 5, line 17). Walt et al further teach the concentration is determined by bead size, substrate size and end use of the array (Column 5, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the teaching of Walt et al to the arrayed microspheres of Sutton et al to obtain the claimed microsphere concentrations for the expected benefit of optimizing the microarray based on bead size, substrate size and end use of the array as suggested by Walt et al (Column 5, lines 1-2).

6. Claims 5-7 and 2- -22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998) in view of Porter et al (U.S. Patent No. 6,146,899, issued 14 November 2000).

Regarding Claims 5-7 and 21, Sutton et al discloses a method for detecting biological samples comprising providing a microarray including a substrate having no preselected sites for microsphere association (Fig. 2-7), coated with a composition of microspheres dispersed in a fluid containing a gelling agent (e.g. polyacrylamide, Column 11, lines 53-57 and Column 12, lines 17-23) the microspheres immobilized at random position on the substrate (Fig. 2-7) and at lease one sub-population of microspheres contain an optical barcode generated from at least

one colorant "associated" with the microspheres (i.e. dye in the coating composition, Column 11, line 57) and further contain a biological probe (e.g. antibody, Column 11, lines 53-57). Sutton et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 16 and Example 1).

Sutton et al further teach the microspheres have luminescent or fluorescent properties (Column 10, lines 58-67) but they do not teach specific imaging methods

However, bright field illumination coupled with a first image collection was well known in the art at the time the claimed invention was made as taught by Porter et al who teach bright field illumination provides additional image collection for facilitated focusing while minimizing photobleaching (Column 4, lines 57-62) and using an algorithm (i.e. comparison) for identification (Column 5, lines 1-18). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the imaging of Sutton et al with the additional bright field illumination taught by Porter et al for the expected benefit of focusing the image while minimizing photobleaching as taught by Porter et al (Column 4, lines 57-62).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998) in view of Chang et al (U.S. Patent No. 4,873,102, issued 10 October 1989).

Regarding Claim 20, Sutton et al discloses a method for detecting biological samples comprising providing a microarray coated with a composition of microspheres dispersed in a fluid containing a gelling agent wherein the microspheres are prepared by known techniques (Column 6, lines 28-54) but they are silent regarding emulsion or coalescence.

However, emulsion polymerization preparation of microspheres was well known in the art at the time the claimed invention was made as taught by Change et al (Example 1, Column 6, lines 25-57) wherein the method provides microspheres of very narrow size range. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the emulsion polymerization of Change et al to the microspheres of Sutton et al to thereby provide microspheres of a uniform size as taught by Chang et al (Column 6, lines 26-28) for the obvious benefits of providing consistent microsphere surface area for surface interaction and thereby controlling interaction uniformity.

8. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998) in view of Porter et al (U.S. Patent No. 6,146,899, issued 14 November 2000) as applied to Claim 21 above and further in view of Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001).

Regarding Claims 23-25, Sutton et al discloses a method for detecting biological samples comprising providing a microarray including a substrate having no preselected sites for microsphere association (Fig. 2-7), coated with a composition of microspheres dispersed in a fluid containing a gelling agent (e.g. polyacrylamide, Column 11, lines 53-57 and Column 12, lines 17-23) the microspheres immobilized at random position on the substrate (Fig. 2-7) and at lease one sub-population of microspheres contain an optical barcode generated from at least one colorant "associated" with the microspheres (i.e. dye in the coating composition, Column 11, line 57) and further contain a biological probe (e.g. antibody, Column 11, lines 53-57). Sutton et al teach the method comprising contacting the array with a biological target, detecting color of the microspheres resulting from target-probe interaction and identifying the sample (Claim 16 and Example 1). Sutton et al teach the method wherein the biological

sample is identified by detecting color associated with a sub-population of microspheres (Claim 16) but they do not teach a plurality of sub-populations each having a unique barcode (Claim 2) the color is generated by two or more colorants (Claim 3) i.e. a mixture of fed, green and blue (Claim 4). However, these elements were well known in the art at the time the claimed invention was made as taught by Walt et al. Walt et al teach a similar method comprising a microarray having microsphere sub-populations at random positions (Column 4, lines 35-58) wherein each sub-population have a unique bar code and unique biological probe generated from a mixture of red, green and blue (Column 14, lines 24-67) wherein the multiple bar code coloring enables encoding of a large number of functionalities while using a small number of colors (Column 14, lines 60-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the plurality of optical bar codes of Walt et al to the microspheres of Sutton et al for the expected benefit of encoding of a large number of functionalities while using a small number of colors as taught by Walt et al (Column 14, lines 60-67).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 21-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 of copending Application No. 10/098,642. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar methods of identifying biological samples and differ only in the instant claims define the coating composition as comprising a gelling agent. However the '642 specification and Claims 1-20 define their preferred embodiment comprise a gelling agent. Hence, the instantly claimed method would have been obvious in view of the '642 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Comments

11. Applicant's intention to take appropriate action when the rejection is no longer provisional is acknowledged.

12. Applicant's amendment and declaration necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 10, 2004